



Practitioner's Docket No.: 868_006

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Yuji HAYASHI, Mitsuhiro MAKINO, Toshiyuki KOUZAKI,
Motohiro TAKEDA and Takahito JOMORI

Ser. No.: 10/530,125

Art Unit: ~~Not assigned~~ 1654

Filed: April 4, 2005

Examiner: ~~Not assigned~~ J. Ha

Confirmation No.: Unknown

For: GLP-1 DERIVATIVE AND PREPARATION THEREOF ABSORBABLE VIA
MUCOUS MEMBRANE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 4, 2005 under "EXPRESS MAIL" mailing label number EV 40699 2693 US.

Janet M. Stevens
Janet M. Stevens

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97(b)

Sir:

The information disclosure statement transmitted herewith is being filed:

- ☐ within three months of the filing date of this national application.
- ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application.
- ☒ before the mailing date of the first Office action on the merits.
- ☐ before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

Respectfully submitted,

May 4, 2005

Date

Kevin C. Brown

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5 - JC03 Rec'd PCT/PTO 04 MAY 2005

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Jane M. Stevens

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. Required copies of the references listed on Form PTO-1449 are attached.

References AE (JP 2002-509082), AJ (CA 2 321 026) and EP 1 062 229 (published as WO 99/46283) correspond to Reference AA (WO 99/46283) which was previously cited in an Information Disclosure Statement filed April 4, 2005. References AD (USP 6,528,486), AF (EP 1 076 066), AG (EP 1 329 458), AH (JP 2003-505347) and EP 1 196 444 (published as WO 01/004156) correspond to Reference AB (WO 01/004156) which was previously cited in the Information Disclosure Statement filed April 4, 2005. References AI (JP 2002-512175) and EP 1 060 191 (published as WO 99/43706) correspond to Reference AC (WO 99/43706) which was previously cited in the Information Disclosure Statement filed April 4, 2005.

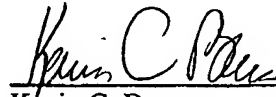
The above information is presented so that the Patent and Trademark Office may, in the first instance, determine any materiality thereof to the claimed invention. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that these references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

May 4, 2005

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Form PTO-1449

US DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/530,125
Filing Date	April 4, 2005
First Named Inventor	Yuji HAYASHI
Art Unit	Not assigned
Examiner Name	Not assigned
Confirmation No.	Unknown
Attorney Docket No.	868_006

U.S. PATENT DOCUMENTS

Exam. Initial	Document Number	Date	Name	Our Docket No.	Class	Sub Class	Filing Date
JH	AD	6,528,486	03/04/2003	Larsen et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Sub Class	Translation	Abstract
JH	AE	2002-509082	03/26/2002	JP			
JH	AF	1.076.066	02/14/2001	EP			
JH	AG	1 329 458	07/23/2003	EP			
JH	AH	2003-505347	02/12/2003	JP			
JH	AI	2002-512175	04/23/2002	JP			
JH	AJ	2 321 026	09/16/1999	CA			
JH	AK	1996-A-027018	01/30/1996	JP			✓

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages etc.)

JH	AL	C.F. Deacon et al., "Dipeptidyl peptidase IV resistant analogues of glucagon-like peptide-1 which have extended metabolic stability and improved biological activity", Diabetologia (1998) 41:271-278
JH	AM	Q. Xiao et al., "Biological Activities of Glucagon-Like Peptide-1 Analogues in Vitro and in Vivo", Biochemistry 2001, 40: 2860-2869
JH	AN	C. Mark B. Edwards et al., "Exendin-4 reduces fasting and postprandial glucose and decreases energy intake in healthy volunteers", Am J Physiol Endocrinol Metab, 281: E155-E161, 2001
JH	AO	Mark K. Gutniak, MD, PHD et al., "GLP-1 Tablet in Type 2 Diabetes in Fasting and Postprandial Conditions", Diabetes Care, Volume 20, Number 12, December 1997, pps. 1874-1879

Examiner:	/Julie Ha/	Date Considered:	5/4/2005
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*In accordance with the Notice dated July 11, 2003 on the PTO website, we are not enclosing copies of any of the above U.S. references.

10/530125

IDS - 04/04/2005

JC13 Rec'd PCT/PTO 04 APR 2005

Practitioner's Docket No.: 868_006

PATENT

#3

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

PCT/JP2003/013020

October 10, 2003

October 11, 2002

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

TITLE OF INVENTION

GLP-1 DERIVATIVE AND PREPARATION THEREOF ABSORBABLE VIA MUCOUS
MEMBRANE

APPLICANT(S) FOR DO/US

Yuji HAYASHI, Mitsuhiro MAKINO, Toshiyuki KOUZAKI, Motohiro TAKEDA and Takahito
JOMORIMail Stop PCT
Attention: DO/US
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Janet M. Stevens

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. Required copies of the references listed on Form PTO-1449 are attached.

Also enclosed is a copy of a corresponding International Search Report bearing a mailing date of January 27, 2004, and the U.S. PTO is directed thereto for a concise statement of possible relevance of the references cited therein.

The above information is presented so that the Patent and Trademark Office may, in the first instance, determine any materiality thereof to the claimed invention. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that these references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

10/530125
JC13 Rec'd PCT/PTO 04 APR 2005

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

April 4, 2005

Date



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10/530125

J013 Rec'd PCT/PTO 04 APR 2005
Complete if known

Form PTO-1449 US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	
				Filing Date Concurrently herewith	
				International Application No. PCT/JP2003/013020	
				International Filing Date October 10, 2003	
				Priority Date Claimed October 11, 2002	
				First Named Inventor Yuji HAYASHI	
				Confirmation No.	
Sheet	1	of	1	Attorney Docket No. 868_006	

U.S. PATENT DOCUMENTS

Exam Initial		Document Number	Date	Name	Our Docket No.	Class	Sub Class	Filing Date

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub Class	Translation	Abstract
JH	AA	99/46283 A1	09/1999	WO				
JH	AB	01/04156 A1	01/2001	WO				
JH	AC	99/43706	09/1999	WO				

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages etc.)

Examiner:	/Julie Ha/	Date Considered:	4/4/2005
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*In accordance with the Notice dated July 11, 2003 on the PTO website, we are not enclosing copies of any of the above U.S. references.

IDS - 03/15/2006

IAP6 Rec'd PCT/PTO 15 MAR 2006

Practitioner's Docket No.: 868_006

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Yuji HAYASHI, Mitsuhiro MAKINO, Toshiyuki KOUZAKI, Motohiro TAKEDA and Takahito JOMORI

U.S. Appln. Ser. No.: 10/530,125

Art Unit: 1615

International Application No.: PCT/JP2003/013020

Examiner: Not assigned

International Filing Date: October 10, 2003

Confirmation No.: 1475

Earliest Priority Date Claimed: October 11, 2002

For: GLP-1 DERIVATIVE AND PREPARATION THEREOF ABSORBABLE VIA MUCOUS MEMBRANE

Commissioner for Patents
P.O. Box 1450
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Janet M. Stevens

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March 15, 2006

Date

Respectfully submitted,

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Janet M. Stevens
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INFORMATION DISCLOSURE STATEMENT

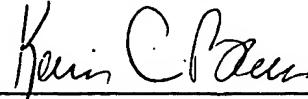
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Respectfully submitted,



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March 15, 2006

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Form PTO-1449 US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				U.S. Application Number	10/530,125
				Int'l Application Number	PCT/JP2003/013020
				Int'l Filing Date	October 10, 2003
				Earliest Priority Date Claimed	October 11, 2002
				First Named Inventor	Yuji HAYASHI
				Art Unit	1615
Sheet	1	of	1	Confirmation No.	1475
				Attorney Docket No.	868_006

U.S. PATENT DOCUMENTS

Exam. Initial		Document Number	Date	Name	Our Docket No.	Class	Sub Class	Filing Date

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub Class	Translation	Abstract
JH	AP	0 978 565 A1	02/09/2000	EP				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages etc.)

Examiner:	/Julie Ha/	Date Considered:	3/15/2006
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